



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CMC Subgroup

January 13, 2026 | 10:30am -12:30pm

Virtual - Microsoft Teams

MEETING PURPOSE

To address clarifying questions about FDA and Industry Chemistry, Manufacturing, and Controls (CMC) review process enhancement proposals.

PARTICIPANTS

FDA

Larry Lee	CDER
KaLonna Maull	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Ivy Sweeney	CDER
Denise Gavin	CDER
Francis Godwin	CDER
Danielle Villata	CDER

Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Drew Sansone	BIO (Alkermes)
Kelly Goldberg	PhRMA
Derek Scholes	BIO

MEETING SUMMARY

The meeting discussion focused on FDA's reaction and alternative approach to Industry's counterproposal to FDA's Facility Lifecycle proposal.

Facility Lifecycle

FDA reviewed slides that outlined an alternative approach to Industry's counterproposal. FDA noted their desire to find common ground, while still aligning with the Agency's value proposition. FDA reiterated their intended focus on proactively resolving facility issues that could potentially lead to complete responses (CRs). FDA also explained their rationale in maintaining the same engagement points that Industry found meaningful but modifying how they are used to ensure FDA resources target facility deficiencies. FDA reviewed the approach the Agency drafted which focused on (1) developing guidance that outlines a pre-submission facility readiness checklist that will help facilitate a meaningful early facility assessment and if needed, discussion between the applicant and FDA on facility-related matters, (2) the ability to modify goal dates if a

company does not meet readiness for inspection criteria and for some cases where facility issues can be resolved if more time is given, and (3) post-inspection engagement. FDA proposed that the pre-submission and post-inspection elements of the proposal be interdependent, rather than individual components that Industry has the option to participate in.

The Agency indicated that facility readiness engagement generally occurs 3-6 months prior to the submission with flexibility depending on clinical urgency. Industry expressed concerns with the goal date extension element before application filing, as industry viewed the determination to extend the goal date was wholly within FDA's discretion and expressed the view that the proposal could extend the goal date unnecessarily when potential issues could be resolved under current review times. Industry noted the risk of a potential extension could discourage companies from participating. Industry requested clarity on FDA's scope for clinical urgency being used as criteria for expediting the pre-submission engagement process and noted that this term would need to be clearly defined. The Agency emphasized the need to build gating criteria on when to have a post-inspection meeting. FDA also noted that the pre-submission engagement would be a resource-intensive touchpoint, requiring guidance for more structured FDA-industry interactions due to an anticipated high volume of requests for pre-submission engagements.

Next Steps

The goal for the next meeting on January 20, 2026, is for both FDA and Industry to continue discussions on FDA's counterproposal approach and share any non-starters for either party.